



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,802	10/09/2001	George H. Small	104410-100	6750
28765 7590 06/04/2009 WINSTON & STRAWN LLP PATENT DEPARTMENT 1700 K STREET, N.W. WASHINGTON, DC 20006				
EXAMINER				
PHILOGENE, PEDRO				
ART UNIT		PAPER NUMBER		
3733				
NOTIFICATION DATE		DELIVERY MODE		
06/04/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@winston.com
mwalker@winston.com

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte GEORGE H. SMALL

Appeal 2009-003517
Application 09/972,802
Technology Center 3700

Decided:¹ June 2, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
MELANIE L. MCCOLLUM, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 17-25, 29, and 31-33. We have jurisdiction under 35 U.S.C. § 6(b).

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

The claims are directed to an umbilical cord clamp and a method of using the clamp. Claims 17, 23, and 29 are representative of the claims on appeal, and read as follows:

17. An umbilical cord clamp comprising:
 - a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other to clamp an umbilical cord between the arms;
 - identification means comprising a gender-identifying color associated with a portion of the clamp that is adapted and configured to facilitate identification of the gender of a baby while the clamp remains on the baby; and
 - a locking portion for securing the arms together when the clamp is closed on the baby's umbilical cord.
23. A method of identifying the gender of a newborn baby which comprises applying the clamp of claim 17 and visually identifying the identification means to determine the gender of the baby.
29. An umbilical cord clamp comprising:
 - a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other for clamping an umbilical cord between the arms;
 - a channel that extends substantially along the length of at least one arm and is open at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed and wherein the depth of the channel increases toward each open end; and
 - a locking portion for securing the arms together when the clamp is closed.

The Examiner relies on the following evidence:

Merritt	US 5,006,830	Apr. 9, 1991
Reynolds et al.	US 5,938,666	Aug. 17, 1999
Dorsey	US 6,132,447	Oct. 17, 2000

Appellant relies on the following evidence:

Declaration of George H. Small, M.D., M.P.H.

The following grounds of rejection are before us for review:

- I. Claims 29 and 31-33 stand rejected under 35 U.S.C. § 112, second paragraph;
- II. Claims 29, 31, and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Reynolds; and
- III. Claims 17-25 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Merritt and Dorsey.

We affirm rejections I and III, but reverse rejection II.

ISSUE (Indefiniteness)

The Examiner finds that claim 29, and the claims dependent thereon, *i.e.*, claims 31-33, are indefinite.

Appellant does not argue the merits of the rejection.

Thus, the issue on appeal is, has Appellant demonstrated that the Examiner erred in finding that claim 29 is indefinite?

FINDINGS OF FACT

FF1 The Examiner rejects claims 29 and 31-33 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention.” (Ans. 3.)

FF2 The Examiner finds that “[i]n claim 29, line 8, the term ‘the depth’ lacks prior antecedent basis.” (*Id.*)

FF3 Appellant does not argue the merits of the rejection, but agrees to correct the informality or to an Examiner’s Amendment correcting the informality (App. Br. 2, n. 1).

ANALYSIS

As Appellant does not argue the merits of the rejection, we summarily affirm it.

CONCLUSIONS OF LAW

As Appellant has not demonstrated that the Examiner erred in finding that claim 29 is indefinite, we summarily affirm the rejection of claims 29 and 31-33 under 35 U.S.C. § 112, second paragraph.

ISSUE (Anticipation)

The Examiner finds that claims 29, 31, and 32 are anticipated by Reynolds.

Appellant contends that Reynolds does not disclose a channel with a depth that increases toward each open end.

Thus, the issue on appeal is: Has Appellant demonstrated that the Examiner erred in finding that Reynolds discloses an umbilical cord clamp having a channel with a depth that increases toward each open end?

FINDINGS OF FACT

FF4 The Examiner rejects claims 29, 31, and 32 under 35 U.S.C. § 102(b) as being anticipated by Reynolds (Ans. 3).

FF5 The Examiner finds that Reynolds teaches all of the limitations of claims 29, 31, and 32 (*id.* at 4).

FF6 With respect to the channel, the Examiner finds that Reynolds teaches:

a channel (21,22) that extends substantially along the length of at least one arm and is open at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed; as set forth in column 4, lines 32-58; and wherein the depth of the channel increases toward each open end; as best seen in Fig.1, (where the incline of the channel 22 increases the depth toward the open end).

(*Id.*)

FF7 Reynolds is drawn to a novel umbilical cord clamp (Reynolds, col. 1, ll. 31-32).

FF8 Figure 1 of Reynolds is reproduced below.

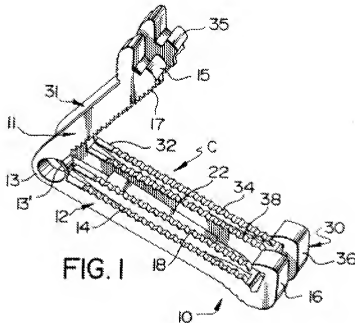


Figure 1 is a perspective view of the clamp of Reynolds in an open position (*id.* at col. 2, ll. 58-59).

FF9 As can be seen in Figure 1, extending between each clamping arm (11 and 31) “is an integrally formed first web sheet (21) while a second web sheet (22) integrally extends between adjacent clamp arms (12) and (32). The two web sheets (21) and (22) constitute the second clamp means (20).” (*Id.* at col. 3, ll. 33-37.)

FF10 Figure 4 of Reynolds is reproduced below.

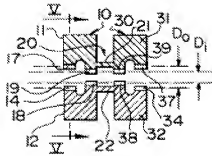


FIG. 4

Figure 4 shows a cross-section of the closed clamp (*id.* at col. 2, l. 67).

FF11 According to Reynolds:

Preferably, the second clamp means (20) has both of its web members (21) and (22) co-planar with, or as close as possible to the root plane of the adjacent inner serrations (19) and (39) in relation to the upper members and (18) and (38) in relation to the lower members--see FIG. 4. Hence, the web sheet (22) is co-planar with the root plane of the serrations (18) and (38) while the web sheet (21) is co-planar with the root plane of the serrations (19) and (39).

(*Id.* at col. 3, ll. 58-65.)

PRINCIPLES OF LAW

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim.

Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001).

ANALYSIS

Appellant argues that Reynolds does not disclose “a channel (21, 22) with a depth that increases toward each open end.” (App. Br. 6-7.)

Specifically, Appellant argues that Reynolds discloses “that the webs (21, 22) are *parallel to and preferably co-planar* to the root plane of opposite interior serrated surfaces, so blood is forced out of the vessels and artery of the cord in *opposite directions*,” and thus “blood is removed out either end of the clamp arms.” (*Id.* at 7 (citing Reynolds, col. 4, ll. 38-42).) Claim 29, Appellant asserts, “recites that the depth of the channel increases toward each open end, which open ends are disposed at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed.” (App. Br. 7.)

The Examiner responds that “Reynolds also stated that the webs could also be as close as possible to co-planar, but not necessarily so,” and that “as can best be seen in FIG. 1, the web 22 forming the channel is slanted, therefore the depth increases toward the open end.” (Ans. 6.)

We find that Appellant has the better argument. The Examiner relies solely on Figure 1, but the disclosure of Reynolds clearly states that “the web sheet (22) is co-planar with the root plane of the serrations (18) and (38) while the web sheet (21) is co-planar with the root plane of the serrations (19) and (39).” (FF11.) Thus, the Examiner’s finding contradicts the Specification. *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000) (noting that “it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”).

CONCLUSIONS OF LAW

We find that Appellant has demonstrated that the Examiner erred in finding that Reynolds discloses an umbilical cord clamp having a channel with a depth that increases toward each open end.

We therefore reverse the rejection of claims 29, 31, and 32 under 35 U.S.C. § 102(b) as being anticipated by Reynolds.

ISSUE (Obviousness)

The Examiner concludes that claims 17-25 are rendered obvious by the combination of Merritt and Dorsey.

Appellant contends that the Examiner has not provided a reason to combine Merritt and Dorsey to arrive at the claimed invention; and further, that the unobviousness of the claimed invention is supported by long-felt need, as evidenced by the Small Declaration.

Thus the issue on appeal is: Has Appellant demonstrated that the Examiner erred in combining Merritt and Dorsey to arrive at the claimed invention; and further; has Appellant demonstrated that when reconsidered in view of the evidence of long-felt need provided in the Small Declaration, did the Examiner err in concluding that the combination of Merritt and Dorsey still render the claims on appeal obvious?

FINDINGS OF FACT

FF12 The invention “relates to methods of using a gender-identifying color on an umbilical cord clamp to facilitate identity recognition.” (Spec. 1.)

FF13 The clamp facilitates gender identification “without resort to other conventional methods such as colored hats or wristbands.” (*Id.* at 5.)

FF14 The Specification teaches:

According to convention, the clamps can be a blue color for boys and a pink color for girls. Any suitable shade can be used. The color can be imbued within the clamp, or painted on or added to an existing clamp, as desired. . . . Preferably, the entire clamp is blue or pink to facilitate gender identification. Indeed, a colored clamp can be identified across a room, such that family members, nurses, or the like can easily use the proper pronoun when referring to the newborn to avoid offending the parents or other overly sensitive relatives. Since a clamp is typically placed on most newborns, it is believed that using a gender-identifying color on the clamp will advantageously avoid the need to resort to various other gender-identifying measures. For example, neonatal units often use gender-colored clothing such as onesies or caps to identify gender, but mistakes can occur when determining gender while the newborn is wearing a diaper. The likelihood of error in identifying gender is significantly reduced when the newborn first arrives in the “au natural” state. Thus, the doctor, nurse, midwife, or other birthing assistant can apply the properly colored clamp to the umbilical cord before or immediately after it is cut to facilitate subsequent gender identification for as long as it takes the cord stump to fall off.

(*Id.* at 10.)

FF15 The Examiner rejects claims 17-25 under 35 U.S.C. § 103(a) as being obvious over the combination of Merritt and Dorsey (Ans. 4).

FF16 The Examiner finds that “Merritt teaches all the limitations [of the claims rejected on this basis], except for an identification means comprising a gender-identifying color associated with [a] portion of the clamp to facilitate identification of the gender of the baby.” (*Id.* at 5.)

FF17 An object of Merritt “is to provide a means of attaching security devices and/or identification marks to newborns which are not easily removable.” (Merritt, col. 3, ll. 1-3.)

FF18 Merritt teaches the use of a clamp for the umbilical cord, wherein the clamp has “a distinctive identification mark thereon.” (*Id.* at col. 2, ll. 49-52.)

FF19 Merritt teaches that the distinctive identifier may be a raised serial number, a bar code, color code, or letter combination (*id.* at col. 4, ll. 12-16). Merritt teaches further that a three-digit serial number could be used, such as 000-499 and 500-999, wherein stock of the first series of clamps should not be replenished until the entire stock is used (*id.* at col. 4, ll. 19-24).

FF20 The Examiner cites Dorsey as evidence of “the use of a device to provide umbilical devices with gender-identifying color coding (blue for boys and pink for girls) for readily recognizable indicia associated with [a] newborn baby.” (Ans. 5.)

FF21 The Examiner concludes that it would have been obvious to use the color coding of Dorsey on the clamp of Merritt as the ordinary artisan “would recognize that this newborn baby indicia would also be advantageous subsequent to umbilical cord severing.” (Ans. 5.)

FF22 The Small Declaration states that “Merritt does not teach anything about identifying groups of children, or a gender-identifying means, or a gender-identifying color, or identifying the gender of a child,” rather, “Merritt teaches only that a unique code of some sort is applied to the clamp to minimize child abductions from a pre-defined secured area.” (Small Decl., ¶6.)

FF23 The Small Declaration further notes that “Dorsey does not suggest that the scissors should remain with the newborn.” (*Id.* at ¶7.)

FF24 The Small Declaration goes on to note that Merritt and Dorsey do not provide any motivation to combine the references as suggested by the Examiner (*id.* at ¶8).

FF25 The Small Declaration states that “the lack of a reliable, essentially error-free manner of determining the gender of a newborn baby without repeated undressing the baby has been a longstanding problem in the obstetric field.” (*Id.* at ¶9.) The Small Declaration goes on to note that “[t]o the best of my knowledge, there has been no solution even to the present time of this problem of misidentifying the gender of newborn children while they are clothed.” (*Id.* at ¶10.)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court rejected a rigid application of a teaching-suggestion-motivation test in the obviousness determination. The Court emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art

would employ.” *Id.* at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). Thus, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). In addition, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416.

“[W]hen a prima facie case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability.” *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is “merely a showing of facts supporting the opposite conclusion.” *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). . . . When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (stating that “all evidence of nonobviousness must be considered when assessing patentability”); *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (“If, however, a patent applicant presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness.”).

In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007). “When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over.” *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976); *In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986) (“If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed”).

A successful showing of long-felt but unresolved need requires objective evidence of three factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *See Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983); *see also In re Gershon*, 372 F.2d 535, 538-39 (CCPA 1967). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988) (“[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved.”). Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971). “[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.” *Texas Instruments Inc. v. ITC*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

ANALYSIS

Appellant argues that Merritt is drawn to “an umbilical cord clamp that contains particular types of *unique* identification marks including a serial code, bar code, color code, or letter combination, each of which has a different *distinctive* mark thereon,” and thus Merritt’s purpose is to provide every baby with a unique identifier (App. Br. 8, citing Merritt, col. 4, ll. 10-24). Merritt, Appellant asserts, at best would require a unique color code “which is presumably at least a pattern of multiple colors.” (App. Br. 8.) Dorsey, Appellant argues, is drawn to a pair of blue or pink labeled scissors used to cut an umbilical cord, which is presented to the parents, and is thus

“merely a novelty item.” (*Id.*) Thus, Appellant contends, the scissors do not remain attached to the baby as a means of identifying the gender (*id.*).

Appellant contends “Merritt and Dorsey simply fail[] to provide those of ordinary skill in the art with any motivation to apply the gender-identifying color of Dorsey in hindsight and apply it to the uniquely coded article of Merritt.” (*Id.* at 9-10 (citing Small Decl., ¶¶7, 8 and 12.)) Appellant argues further that “Dorsey actually *teaches away* from Merritt,” as Merritt teaches that every clamp has a unique identifier, whereas Dorsey teaches a pair of scissors the use of gender-identification colors on a pair of scissors that do not remain with the baby, which is not a sufficient universe of colors to provide an unique security code (App. Br. 10 (citing Small Decl., ¶¶6-8)).

Appellant’s arguments are not convincing. Merritt teaches the use of an umbilical cord clamp having a unique code, such an alphanumeric code or a color code for identification purposes, as well as identification purposes (FF17-FF19). Dorsey is merely evidence that is well known in the art to use a color code to identify the gender of a baby, such as pink for a girl and blue for a boy. Thus, we agree with the Examiner that it would have well within the level of skill in the art to color code an umbilical clamp to differentiate between girl and boy babies. That conclusion is supported by Appellant’s Specification, where it noted that the clamp facilitates gender identification without the use of conventional means such as wristbands (FF13).

Moreover, as to the claims to the clamp *per se*, i.e., claims 17-22, the use of the clamp to identify the gender of a baby is a statement only of intended use, and Merritt teaches the use of color coding (FF19). While

Appellant argues that Merritt teaches that such a color coding would have to be a unique color code which is presumably at least a pattern of multiple colors, Merritt does teach the use of a three digit serial number, wherein stock of a series should not be replenished until the entire series is used (FF19). Given Merritt's teaching regarding color coding, it would have well been within the level of skill in the art to color code the different series in order to prevent overlap and mistakes.

The Small Declaration restates arguments in the Appeal Brief. However, these arguments are not found to be convincing for the reasons set forth above.

As to claim 21, Appellant argues that the claim requires an identification means that further includes an alpha-numeric indicia, security apparatus, or bar code (App. Br. 11). Thus, Appellant asserts, "[w]hile claim 21 recites a type of identifier like that or [sic] Merritt, it clearly distinguishes the gender-identifying color of parent claim 17 from this identification means." (*Id.*)

As to claim 23, Appellant argues that the claim is drawn to applying the clamp of 21 to a baby and visually analyzing the identification means to determine the gender of the baby, and that neither Merritt nor Dorsey, either alone or as combined, suggests analyzing the gender-identifying color on the clamp to determine the gender of the baby (App. Br. 11-12).

As to claim 24, Appellant argues that the claim "recites a method of identifying a newborn baby by applying the clamp including an alpha-numeric indicia, security apparatus, or a bar code, and analyzing the identification means to determine the mother of the newborn so as to

minimize the chance of misidentification of the baby or mother thereof.” (App. Br. 12.) Appellant contends that the references relied upon by the Examiner “do not disclose correlating and identifying the mother from a gender-identifying color clamp that also includes such an alpha-numeric indicia, security apparatus, or a bar code.” (*Id.*)

As noted above, given that it is well known to use color coding to identify the gender of a baby, it would have been obvious to add color coding to the umbilical clamp of Merritt to aid in identification of a newborn, which includes its gender. Thus, we do not find Appellant’s arguments as to claims 21, 23, and 24 convincing.

Appellant argues further that the Declaration evidences “the existence of a long-felt, but unsolved need, in the art for the claimed clamps and methods.” (App. Br. 12 (citing Small Decl., ¶¶9-12).) The Small Declaration, however, merely states that there was a long-felt need satisfied by the claimed invention, but provides no objective evidence or underlying facts to support the opinion evidence. In addition, the Specification notes that it was conventional to use wristbands (FF13), which would allow one to identify sex without resort to removing the diaper, thus contraindicating Appellant’s opinion evidence as to the existence of an unsolved, long-felt need.

CONCLUSIONS OF LAW

We conclude that Appellant has not demonstrated that the Examiner erred in combining Merritt and Dorsey to arrive at the claimed invention; and further, Appellant has not demonstrated that when reconsidered in view

of the long-felt need as evidenced by the Small Declaration, that the Examiner err is concluding that the combination of Merritt and Dorsey still render the claims on appeal obvious.

We therefore affirm the rejection of claims 17-25 under 35 U.S.C. § 103(a) as being obvious over the combination of Merritt and Dorsey.

SUMMARY

We thus:

Affirm the rejection of claims 29 and 31-33 under 35 U.S.C. § 112, second paragraph;

Reverse the rejection of claims 29, 31, and 32 under 35 U.S.C. § 102(b) as being anticipated by Reynolds; and

Affirm the rejection of claims 17-25 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Merritt and Dorsey.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON DC 20006